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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/979,558	MARUYAMA ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☒ Claim(s) *4 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1101* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence search results* .

DETAILED ACTION

1. This application is a 371 of PCT/JP00/03372, filed May 25, 2000. It is noted that the International Search Report and an English translation of the International Preliminary Examination Report for PCT/JP00/03372 have been received and considered.

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-7, in the Amendment and Response filed June 5, 2003, is acknowledged. The traversal is on the following ground(s).

First, the response argues that the restriction is improper because unity of invention was not found to be lacking during search and examination of applicants' PCT application by the Japanese Patent Office. The response further argues that the results of the PCT search provide evidence that all of the claims may be searched together. The response also urges that all of the claims do share a special technical feature, specifically, "special technical features relating to SEQ ID NO: 1." The response states that this "special technical feature" represents "a contribution made by each of the inventions as a whole over the prior art." Finally, the response indicates that it is applicants' belief that the instant situation is analogous to Example 13 of Annex B, Part 2, as "the Group II bacteria comprise SEQ ID NO: 1."

Applicants' arguments have been thoroughly considered but are not persuasive. First, it is noted that the fact that the Japanese office chose to search and examine all of the claims in applicants' PCT application does not provide evidence that unity of

invention is present; further, the actions taken by that office are not binding during examination of an application for a U.S. patent. It is again noted that unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical feature" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution that an invention considered as a whole makes over the art. In the instant case, a shared special technical feature is lacking, for the reasons given in the prior Office action. While Applicants' argument focuses on SEQ ID NO: 1, neither Group I nor Group II is limited to SEQ ID NO: 1. Each invention, considered as a whole, is much broader. For example, Group I encompasses probes comprising any subsequence of SEQ ID NO: 1, while Group II encompasses numerous types of bacterial strains, the majority of which would not be expected to include SEQ ID NO: 1. While Applicants argue that the instant claims are analogous to those of Example 13, this is not the case. In Example 13, each claim requires the presence of a filament, and the example states "The special technical feature common to all the claims is the filament." However, while each of the Example 13 claims recites and requires "the filament," neither the invention of the Group I claims, nor the invention of the Group II claims, when considered as a whole, is actually limited to SEQ ID NO: 1. Further, as Group I, considered as a whole, does not make a contribution over the art, by definition, unity of invention is lacking. Finally, it is noted that while the issue of search burden is not one of the criteria applied when considering restriction of a 371 application, Groups I and II do in fact require different searches. For example, while

examination of Group I requires a search for detection methods employing nucleic acids, examination of Group II would require a search for "aerobic, gram-negative, nonmotile, colorless, non-sporulating and oxidase positive" bacteria.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Amendment and Response of June 5, 2003.

Specification

3. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

4. Claims 4 and 5 are objected to because of the following informalities: *glacincola* is misspelled "*glacinocola*". Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-4 and 6 as written do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and naturally occurring products. In the absence of the hand of man, the

naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). See MPEP 2105. Regarding claims 2-4 and 6, it is particularly noted that the specification does not provide limiting definitions of the terms "oligonucleotide," "probe," or "oligonucleotide probe," and that the specification clearly indicates that the term "probe" encompasses unlabeled molecules (see, e.g., page 11, which states "a probe may be labeled").

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2 and 4-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for oligonucleotide probes consisting of or comprising SEQ ID NO: 2, and for methods of detecting *P. pacificensis* and/or *P. glacincola* in which such probes are employed, does not reasonably provide enablement for probes comprising any "part of" SEQ ID NO: 1, for methods of detecting *P. pacificensis* and/or *P. glacincola* that employ such other probes, or for methods of detecting "analogs" of *P. pacificensis* and *P. glacincola* with SEQ ID NO: 2 or other probes comprising "part of" SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (*MPEP* 2164.01(a)).

Claims 2, 4, and 6 encompass oligonucleotide probes that comprise any "part of the base sequence of SEQ ID NO: 1." Claims 5 and 7 are drawn to methods in which such a probe is employed in "detecting or identifying at least one bacterium selected from" *P. pacificensis*, *P. glacincola*, and "analogs thereof" (claim 5) or in "specifically detecting or identifying a bacterium belonging to" *P. pacificensis* (claim 7).

It is unpredictable as to whether one of skill in the art could make and use applicants' invention in a manner reasonably commensurate with the instant claims. The specification exemplifies the successful use of a single subsequence of SEQ ID NO: 1, SEQ ID NO: 2, in the detection (as well as the differentiation) of *P. pacificensis and P. glacincola* (see entire specification, particularly Examples 3-5). However, the instant claims are sufficiently broad so as to encompass probes comprising any subsequence of any length selected form SEQ ID NO: 1, and the use of any such probe in the detection of not only *P. pacificensis* and/or *P. glacincola*, but "analogs thereof." The specification indicates that a wide variety of bacterial are considered to be analogs of these two species, including unidentified bacteria and other bacteria for which no

data is provided in the specification (see page 12). The specification only exemplifies the successful detection of two particular species (*P. pacificensis* and *P. glacincola*) with a single species of probe (SEQ ID NO: 2). Lacking guidance from the specification, one of skill in the art may look to the teachings of the prior art for further guidance and enablement of a claimed invention. In the instant case, the prior art as exemplified by Bowman et al (Applied and Environmental Microbiology 63(8):3068-3078 [8/1997]) teaches the use of a universal primer sharing regions of identify with SEQ ID NO: 1 in detection of *P. glacincola*, as well as *P. immobilis* (one species identified in the specification as an "analog"). Accordingly, the teachings of the prior art are sufficient to enable the use of such well-known probes. However, neither the teachings of the specification nor of the art enable the use of the vast majority of probes encompassed by the claims in identification of *P. pacificensis*, *P. glacincola*, or "analogs thereof." Further, the specification does not provide any evidence that "analogs" of *P. pacificensis* and *P. glacincola* may be successfully detected with SEQ ID NO: 2 (in contrast, the data reported in Tables 7 and 8 indicates that this probe does not detect other *Psychrobacter* species). While it is clearly within the ability of one of skill in the art to conduct further experimentation aimed at identifying additional subsequences of SEQ ID NO: 1 that may be useful in specific identification of *P. pacificensis* and/or *P. glacincola* (and possibly other species considered to be analogs thereof), the outcome of such experimentation cannot be predicted. Accordingly, it is unpredictable as to whether any quantity of experimentation would result in the identification of any other species that may actually be used successfully in the methods disclosed by applicants. Accordingly,

while the teachings of the specification are enabling for oligonucleotide probes consisting of or comprising SEQ ID NO: 2, and for methods of detecting *P. pacificensis* and/or *P. glacincola* in which such probes are employed, it would require undue experimentation to make and use applicants' invention in a manner reasonably commensurate with the instant claims.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4-5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 are indefinite over the recitation of the limitation "analogs thereof." While the specification provides examples of types of bacteria that may be considered analogs (see page 12), no limiting definition for this terminology is provided, and the term "analog" is not a standard term used in the art to identify, e.g., a particular subset of bacteria as it relates to other bacteria of a genus or species. Accordingly, this recitation does not clearly apprise one of skill in the art as to what bacteria would actually be encompassed by the claims.

Claim 5 is rejected as being incomplete for omitting essential steps. See MPEP § 2172.01. The claim requires "detecting or identifying" bacteria, but does not actually recite any steps that accomplish detecting or identifying. The recitation "using an oligonucleotide probe" does not indicate to one of skill in the art the manner in which a probe is to be used to achieve detection or identification (or even make clear that the

probe is actually used in a manner that accomplishes detection or identification). Accordingly, the claim as written is incomplete.

Claim 7 is rejected as being incomplete for omitting essential steps. See MPEP § 2172.01. The claim requires "detecting or identifying" bacteria, but does not actually recite any steps that accomplish detecting or identifying. The recitation "using an oligonucleotide probe" does not indicate to one of skill in the art the manner in which a probe is to be used to achieve detection or identification (or even make clear that the probe is actually used in a manner that accomplishes detection or identification). Accordingly, the claim as written is incomplete.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Maruyama et al (Marine Biology 128:705-711 [1997])("Maruyama et al-1").

Maruyama et al-1 disclose the universal 16S rRNA primer, 27f (see page 707, left column). It is an inherent property of this primer that it is a probe comprising "part of the base sequence of SEQ ID NO: 1" (for example, nucleotides 5-11 and 13-17 are identical to nucleotides 1-7 and 9-13 of SEQ ID NO: 1, respectively). Regarding claims 4 and 6, it is further noted that the recitation in the claims of an intended use for the

claimed products (specifically, the recitation in claim 4 "for detecting...analogs thereof" and in claim 6 "for specifically detecting....*Psychrobacter pacificensis*") does not result in a structural difference between the claimed invention and the molecule taught by Maruyama et al-1, and further that the molecule of Maruyama et al-1 is capable of performing the intended uses recited in the instant claims. (See MPEP 2111.02 for a further discussion of the weight given to statements reciting purpose or intended use of a claimed product). Accordingly, Maruyama et al-1 anticipate claims 2, 4, and 6.

Regarding claim 5, Maruyama et al-1 employ primer 27f in the identification of a variety of bacteria including *Psychrobacter immobilis* (see entire reference, particularly page 707, left column, and page 709). As *P. immobilis* is disclosed in the specification as being an "analog" of *P. pacificensis* and *P. glacincola* (see page 12), Maruyama et al-1 also anticipate claim 5.

12. Claims 2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowman et al (Applied and Environmental Microbiology 63(8):3068-3078 [8/1997]), as evidenced by Maruyama et al-1.

Bowman et al disclose the universal 16S rRNA primer, 27f (see page 3069, right column). Maruyama et al-1 provide evidence that it is an inherent property of this primer that it is a probe comprising "part of the base sequence of SEQ ID NO: 1" (for example, nucleotides 5-11 and 13-17 are identical to nucleotides 1-7 and 9-13 of SEQ ID NO: 1, respectively). Regarding claims 4 and 6, it is further noted that the recitation in the claims of an intended use for the claimed products (specifically, the recitation in claim 4 "for detecting...analogs thereof" and in claim 6 "for specifically

detecting....*Psychrobacter pacificensis*") does not result in a structural difference between the claimed invention and the molecule taught by Bowman et al, and further that the molecule of Bowman et al is capable of performing the intended uses recited in the instant claims. (See MPEP 2111.02 for a further discussion of the weight given to statements reciting purpose or intended use of a claimed product). Accordingly, Bowman et al anticipates claims 2, 4, and 6.

Regarding claim 5, Bowman et al employ primer 27f in the identification of a variety of bacteria including *Psychrobacter glacincola* and *Psychrobacter immobilis* isolates (see entire reference, particularly page 3069, 3071, and 3074). page 707, left column, and page 709). *P. glacincola* is recited in claim 5, and *P. immobilis* is disclosed in the specification as being an "analog" of *P. pacificensis* and *P. glacincola* (see page 12). Accordingly, Bowman et al also anticipate claim 5.

13. Claim 1-7 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Maruyama et al (International Journal of Systemic and Evolutionary Microbiology 50:835-846 [3/2000])("Maruyama et al-2"), as evidenced by GenBank Accession No. AB016057 (5/10/2000). It is noted that the inventive entity of the instant invention is distinct from the authorship of the Maruyama et al-2 reference and that this rejection may be overcome by the filing of a Katz-type declaration or by establishing priority of the invention to May 25, 1999 by filing a certified translation of priority document JP 11/145342.

Maruyama et al-2 disclose *P. pacificensis* strain NIB P2K6(T), and disclose that the 16S rDNA sequence of this strain corresponds to GenBank Accession No.

AB016057 (see entire reference, particularly Table 1 on page 837). It is an inherent property of GenBank Accession No. AB016057 that it is identical to instant SEQ ID NO: 1 (see the alignment of these 2 sequences). Accordingly, Maruyama et al-2 disclose a 16S rDNA comprising instant SEQ ID NO: 1. Maruyama et al-2 further disclose the use of bacterial nucleic acids comprising this sequence as a probe in DNA-DNA hybridization experiments that result in both detection of *P. pacificensis* and differentiation of *P. pacificensis* from related organisms (see entire reference, particularly pages 839 and 841). Accordingly, Maruyama et al-2 clearly anticipate claims 1-7.

With further regard to claim 1, while the instant claim does not require, e.g., an isolated molecule consisting of SEQ ID NO: 1, it is further noted that Maruyama et al-2 disclose that 16S rDNA sequences were obtained by sequencing purified PCR products obtained by amplification with universal PCR primers 27f and 1525r (see page 838, right column); it is an inherent property of the isolated PCR product obtained in this manner using *P. pacificensis* strain NIB P2K6(T) nucleic acids that it constitutes an isolated 16S rDNA consisting of SEQ ID NO: 1.

14. Claim 1 is rejected under 35 U.S.C. 102(a) as being clearly anticipated by Maruyama et al (Applied and Environmental Microbiology 66(5):2211-2215 [5/2000; available 5/10/2000])("Maruyama et al-3"), as evidenced by GenBank Accession No. AB016057 (5/10/2000). It is noted that the inventive entity of the instant invention is distinct from the authorship of the Maruyama et al-3 reference and that this rejection may be overcome by the filing of a Katz-type declaration or by establishing priority of

the invention to May 25, 1999 by filing a certified translation of priority document JP 11/145342, and/or by establishing priority of the invention to March 30, 2000 by filing a certified translation of PCT/JP00/02045.

Maruyama et al-3 disclose *P. pacificensis* strain NIB P2K6(T)(see page 2211, right column). It is an inherent property of this strain that its 16S rDNA is identical to instant SEQ ID NO: 1, as evidenced by GenBank Accession No. AB016057 (see the sequence and source information provided in the GenBank entry, as well as the alignment of these 2 sequences). Accordingly, Maruyama et al-3 disclose a 16S rDNA comprising instant SEQ ID NO: 1, and thereby clearly anticipate the claimed invention.

15. Claims 2-7 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Maruyama et al (Maruyama et al-3). It is noted that the inventive entity of the instant invention is distinct from the authorship of the Maruyama et al-3 reference and that this rejection may be overcome by the filing of a Katz-type declaration or by establishing priority of the invention to May 25, 1999 by filing a certified translation of priority document JP 11/145342, and/or by establishing priority of the invention to March 30, 2000 by filing a certified translation of PCT/JP00/02045.

Maruyama et al-3 disclose a probe comprising instant SEQ ID NO: 2 (see entire reference, particularly page 2212, left column, sequence of the "Psypac 469" probe), and disclose the specific detection of *P. pacificensis* using said probe (see entire reference, particularly pages 2212-2214). Accordingly, Maruyama et al-3 clearly anticipate claims 2-7.

Conclusion

16. Sequence search results are cited to show the sequence identity shared between GenBank Accession No. AB016057 and instant SEQ ID NO: 1.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
September 5, 2003